

K082799

JAN 27 2009

510(k) Summary

Date of Summary

January 19, 2009

Submitter

Company Name:	Paragon Vision Sciences
Address:	945 East Impala Ave., Mesa, AZ 85204
Phone:	480-892-7602
Fax:	480-892-3226
Registration:	Owner Operator # 9024618

Manufacturer Information

Company Name:	Paragon Vision Sciences
Address:	945 East Impala Ave., Mesa, AZ 85204
Phone:	480-892-7602
Fax:	480-892-3226
Registration:	Site Registration #2020433

Official Correspondent

Name:	William E. Meyers, Ph.D.
Address:	% Paragon Vision Sciences
Address:	945 East Impala Ave., Mesa, AZ 85204
Phone:	480-507-7606
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Device Name

Trade Name	HDS HI 1.54
USAN Name	pahrifocon A

Classification & Ophthalmic Devices Branch

Common Name:	Contact lens
Product Code:	HQD
Classification Name:	Rigid gas permeable contact lens for daily wear
Classification Panel:	Ophthalmic
Reference:	21 CFR 886.5916; rigid gas permeable contact lens, Class II - daily wear contact lens

Marketed device to which equivalence is claimed is FluoroPerm 30 (paflucocon c).

HDS HI 1.54 (pahrifocon A) rigid gas permeable contact lenses for daily wear are available as lathe cut contact lenses with spherical, aspheric, bifocal or toric anterior and/or posterior; or, bitoric surfaces in clear and tinted versions. The posterior curve is selected so as to properly fit an individual eye and the anterior curve is selected to provide the necessary optical power to correct refractive error. A peripheral curve system on the posterior surface allows tear exchange between the lens and the cornea.

The HDS HI 1.54 rigid gas permeable contact lens material is a thermoset copolymer derived from acrylate, silicone acrylate, and fluorosilicone acrylate monomers, dimers and oligomers.

The HDS HI 1.54 rigid gas permeable tinted lenses offer a handling aid for locating the lens and may be plasma treated.

Refractive Index	1.54
Luminous Transmittance ⁺ (Clear)	97%
Luminous Transmittance (Blue)	93%
Luminous Transmittance (Green)	94
Wetting Angle (Receding Angle) ⁺⁺	44°
Wetting Angle (Sessile Drop) ⁺⁺⁺	77°
Specific Gravity	1.12
Hardness (Shore D)	84
Water Content	<1%
Oxygen Permeability*	22x10 ⁻¹¹ Dk at 35° C

⁺ Determination of the Spectral and Luminous Transmittance, ISO 8599:1994

⁺⁺ Adapted from: A New Method for Wetting Angle Measurement; Madigan, et. al., International Eyecare, 01/1998, vol. 2, no. 1, p. 45

⁺⁺⁺ Sessile Drop Technique per ANSI Z80.20. 8.11

*(cm²/sec) (mL O₂) / (mL x mm Hg) ISO/ANSI Method, ISO 9913-1

Indications for use

HDS HI 1.54™ rigid gas permeable contact lenses are indicated for daily wear as recommended by the eye care practitioner.

HDS HI 1.54™ rigid gas permeable spherical, aspheric and bifocal contact lenses are indicated for the correction of refractive ametropia in not-aphakic persons with non-diseased eyes that are nearsighted (myopic), farsighted (hyperopic), and may exhibit corneal astigmatism up to 4.00 diopters that does not interfere with visual acuity. HDS HI 1.54™ toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters.

HDS HI 1.54™ bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.

HDS HI 1.54™ contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery, in otherwise non-diseased eyes.

The above indication for use is identical to that of the predicate device except for replacement of visual acuity with refractive ametropia as requested.

Property	HDS HI 1.54 Un-irradiated	HDS HI 1.54 Irradiated	FluoroPerm 30
Specific Gravity	1.12	-	1.14
Refractive Index	1.54	1.54	1.466
% Light Transmittance*	93	94	94
% Water Content	1	1	< 1
Oxygen Permeability(Dk)**	22	22	30
Hardness (Shore D)	84	84	84
Modulus, kgf/cm ²	16,990	19,000	16,660
Flexure Stress, kgf/cm ²	559	700	505
Flexure Strain, %	4	5	4
Toughness, gf-mm	429	560	440
Preservative Uptake, µg/ cm ²	CDG 0.35 PAPBG 0.01	- -	CDG 0.80 PAPBG 0.01
Preservative Release, µg/ cm ²	CDG 0.02 PAPBG 0.01	- -	CDG 0.05 PAPBG 0.01
Soxhlet Extractables, wt %,Hexane / Water	3.87 / 0.66	3.44/0.66	3.45 / 0.10
Residuals, wt, %, Acetonitrile, VC-VP	2.67-0.72	2.36-0.15	- -
Wetting Angle Receding [†] /Sessile Drop [‡]	44/77	-	13/68

*Blue tinted material; Power = plano, Center Thickness = 0.15 ± 0.02 mm

** $(\text{cm}^2/\text{sec}) (\text{mL O}_2) / (\text{mL} \times \text{mm Hg})$ ISO/ANSI Method, ISO 9913-1

[†] Adapted: A New Method for Wetting Angle Measurement; Madigan, et. al., International Eyecare, 01/1998, vol. 2, no 1, p. 45

[‡] ANSI Z80.20-1998 (8.11.1 – 8.11.1.4)

Summary of Non clinical test results

In addition to the non-clinical tests indicated by the table above, studies were performed on the saline extractives following the method of the USP <88> BIOLOGICAL REACTIVITY TEST and toxicological procedures for Ocular Irritation, Systemic Toxicity and Cytotoxicity (ISO 10993-5, ISO 10993-10, ISO 10993-11). These studies found the saline extractives to be small and in line with the predicate material and no indications of toxicity nor irritation were observed in the procedures.

Summary of clinical results

Seventy six (76) subjects (152 eyes) were enrolled and dispensed in the multisite, randomized, double masked clinical study to provide data that support the presumption of equivalence of the HDS HI 1.54™ investigational

lenses to a historical control contact lens. Sixty four (64) subjects (84.2%) completed the study and 12 subjects (15.8%) were discontinued. The population demographics were similar to previous contact lens studies.

Of the ten Test subjects who discontinued, Difficulty Cleaning Lenses (3 subjects) and Poor Comfort (2 subjects), Poor Vision (1 subject) and Poor Vision and Poor Comfort (2 subjects) accounted for 80% of the discontinuations. Two Control subjects discontinued, one for Loss of Interest and one for Poor Comfort

There were no adverse events reported during the study. The only study related complications were slit lamp findings of grade 3 for injection. Each of these resolved without complication.

Slit lamp findings were reported at frequencies within expected values and the positive slit lamp observations were primarily grade 1 (trace). Staining and injection were reported most frequently. Subject reports of no symptoms were lowest at the 1 week visit for both the Completed Test and Control eyes and then increased over the remainder of the study. Discomfort was reported most frequently (13.7% of Completed Test eye visits and 12.3% of Completed Control Eye visits).

Lens comfort was rated as an average of 4.04 (very good) for the Completed Test eyes and 4.07 (very good) for the Completed Control eyes. This compared to a baseline value of 3.96 for the Test eyes and 4.23 for the Control eyes with the pre-study habitual correction.

Keratometry changes were within 1.00 diopter for 93.1% of the Completed Test eyes and 96.4% of the Completed Control eyes. Manifest refraction changes were within 1.00 diopter for 97.9% of the Completed Test eyes and 98.2% of the Completed Control eyes.

One eye of the 63 Completed Test eyes targeted for full distance vision was reported to show a decrease in contact lens visual acuity from the baseline best corrected visual acuity of greater than 0.20 logMAR. The reason for the loss was a reported baseline measurement error. One eye of the 48 Completed Control eyes targeted for full distance vision was reported to show a decrease in contact lens visual acuity from the baseline best corrected visual acuity of greater than 0.20 logMAR. The reason cited for the decrease was lenses being switched eye for eye.

Average lens wearing time was stable at over 13 hours per day for the Completed Test and Control subjects and showed a decrease over time for the discontinued eyes.

Forty nine (49) lens replacements were made for 40 of the 152 eyes dispensed in the study. The replacements were predominantly for deposits (8) or parameter and power change (21) which together account for 59% of the lens replacements. Discomfort was cited for 18.4% (5 test and 4 control lenses) of the lens replacements. Five lenses (10%) were replaced due to loss.

The results of the clinical evaluation of the Paragon HDS HI 1.54™ contact lenses provide evidence of substantial equivalence to the historical control, Paragon Fluorperm® 30 contact lenses.

Conclusions drawn from studies

The conclusions drawn from the nonclinical and clinical tests (discussed above) are that the device is as safe, as effective, and performs as well as or better than the predicate device .

Appendix Two

Indications for Use Form



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 2009

Paragon Vision Sciences
William E. Meyers, Ph.D.
Vice President, Science and Technology
945 East Impala Ave.
Mesa AZ 85204

Re: K082799

Trade/Device Name: HDS HI 1.54 (pahrifocon A) Rigid Gas Permeable Contact Lens for daily wear

Regulation Number: 21 CFR 886.5916

Regulation Name: Rigid gas permeable contact lens

Regulatory Class: II

Product Code: HQD

Dated: January 19, 2009

Received: January 21, 2008

Dear Dr. Meyers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Malvina B. Eydelman, M.D.

Director

Division of Ophthalmic and Ear, Nose
and Throat Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

Indications Statement

510(k) Number : K082799

Device Name: **HDS HI 154**

Indications For Use:

HDS HI 1.54™ rigid gas permeable contact lenses are indicated for daily wear as recommended by the eye care practitioner.

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HDS HI 1.54™ toric contact lenses are indicated to correct astigmatism of up to 6.00 diopters.

HDS HI 1.54™ bifocal lenses are indicated to treat presbyopia up to +4.00 D add power.


HDS HI 1.54™ contact lenses are indicated for management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty, radial keratotomy, or LASIK surgery, in otherwise non-diseased eyes.

**PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON
ANOTHER PAGE IF NEEDED)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The Counter Use _____

(Optional Format 1-2-96)



(Division Sign-Off)
Division of Ophthalmic and Ear,
Nose and Throat Devices

510(k) Number K082799